Summary of Safety and Clinical Performance

Insulet Corporation

Omnipod® 5 Automated Insulin Delivery System

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This Summary of Safety and Clinical Performance (SSCP) offers public access to a summary of the safety and clinical performance of the device.

The information presented below is for people with diabetes and their families / guardians / carers. A more extensive summary prepared for healthcare professionals is available to healthcare personnel upon request.

The SSCP is not meant to give general advice on medical treatment. Please contact your healthcare professional if you have questions about your medical condition. You can ask your healthcare professional about the use of the device in your situation. This SSCP is not intended to replace Instructions for Use for the device.

DEVICE IDENTIFICATION AND GENERAL INFORMATION

DEVICE TRADE NAME(S)

Omnipod® 5 Automated Insulin Delivery System

MANUFACTURER'S NAME, ADDRESS, AND SINGLE REGISTRATION NUMBER

Insulet Corporation

100 Nagog Park,

Acton, MA 01720

US-MF-000007948

BASIC UNIQUE DEVICE IDENTIFICATION-DEVICE IDENTIFIER

0385083000145

a) YEAR WHEN THE DEVICE WAS FIRST CE-MARKED

2022

INTENDED USE OF THE DEVICE

INTENDED PURPOSE

The Omnipod 5 Automated Insulin Delivery System is used to manage type 1 diabetes in people 2 years of age and older who take insulin. Omnipod 5 can deliver U-100 rapid-acting insulin through a cannula (small tube) placed just under the skin.

The Omnipod 5 System can work as an automated insulin delivery system when used with certain glucose sensors, also called continuous glucose monitoring (CGM) systems.

When used in Automated Mode, Omnipod 5 is designed to help people with type 1 diabetes reach glucose targets set with their healthcare providers. It can increase, decrease, or pause insulin delivery based on sensor glucose values. Omnipod 5 works to keep glucose close to a chosen target. The choices for Target Glucose are between 110 and 150 mg/dL (6.1 and 8.3 mmol/L).

The goal of the System is to reduce swings in glucose. Fewer swings mean less low and high glucose, less severe lows and highs, and shorter lengths of time spent low and high.

Omnipod 5 can also work in a Manual Mode that delivers insulin like a standard insulin pump. A standard insulin pump is programmed to dose a certain amount of insulin per hour. In Manual Mode, sensor glucose is not used to make any automatic adjustments.

Each Omnipod 5 System should be used by only one person and should not be shared.

INDICATION(S) AND INTENDED/TARGET POPULATION(S)

Indications for use and target population:

The Omnipod 5 Automated Insulin Delivery System is recommended for people who:

- Have type 1 diabetes
- Are 2 years of age and older
- Have a prescription for Novolog®/NovoRapid®, Humalog® and Admelog®/Insulin lispro Sanofi® U-100 insulin
- Can understand and follow the instructions for use

CONTRAINDICATIONS AND/OR LIMITATIONS

The Omnipod 5 System is NOT recommended for people who:

- Are unable to monitor blood glucose levels as recommended by their healthcare provider
- Are unable to maintain contact with their healthcare provider
- Are unable to use the Omnipod 5 System according to instructions
- Are taking hydroxyurea as it could lead to falsely elevated CGM values and result in over-delivery of insulin that can lead to severe hypoglycaemia
- Do NOT have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms, and reminder

Device components including the Pod, CGM transmitter, and CGM sensor must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. In addition, the Controller should be placed outside of the procedure room. Exposure to MRI, CT, or diathermy treatment can damage the components.

DEVICE DESCRIPTION

DEVICE DESCRIPTION AND MATERIAL/SUBSTANCES IN CONTACT WITH PATIENT TISSUES

The Omnipod 5 Automated Insulin Delivery System is an insulin-only system. It is a hybrid-closed loop system, which means that you have to interact with it to give it information about meals and to give a bolus dose of insulin.

Omnipod 5 can operate in two modes. In Manual Mode, it works as a standard insulin pump using pre-programmed basal rates, set by you and your healthcare provider. In Automated Mode, it automatically raises, lowers, or pauses insulin based on rules from the algorithm (software) inside the pump. The algorithm uses your current sensor glucose value and trend, your Total Daily Insulin (TDI), and your chosen Target Glucose to change your insulin.

At any time, in either Mode, you have the option to take a bolus dose of insulin, either by entering an amount for your dose or by using the Bolus Calculator to suggest a dose for you. The Bolus Calculator can use either your sensor glucose value and trend or a blood glucose reading from a fingerstick. The calculator also looks at carbohydrates you enter and your Target Glucose to give its bolus suggestion.

Omnipod 5 has two parts:

- Omnipod 5 Pod (Infusion pump with automated insulin delivery algorithm),
- Omnipod 5 App installed on the Controller, (also known as the Insulet-provided locked-down controller).

In addition, Omnipod 5 can be used with a compatible continuous glucose monitoring system (currently the Dexcom G6 Continuous Glucose Monitoring (CGM) System). The aforementioned CGM device is sold separately. Use of a compatible continuous glucose monitoring (CGM) system is required to use Omnipod 5's Automated Mode.

The figure below shows the Omnipod 5 System when used with Dexcom G6.

The outside of the Pod sticks to your skin for 3 days with polyester adhesive tape. The Pod delivers insulin under your skin through a small tube called a cannula. It inserts the cannula into your skin with a stainless-steel insertion needle. The needle does not stay in your skin.

INFORMATION ABOUT MEDICINAL SUBSTANCES IN THE DEVICE, IF ANY

Pods do not come prefilled with insulin. There is no drug inside the Pod when you open it.

The Omnipod 5 System can be used with Novolog®/NovoRapid®, Humalog® and Admelog®/Insulin lispro Sanofi® U-100 insulin.

DESCRIPTION OF ACCESSORIES/OTHER DEVICES AND PRODUCTS, WHICH ARE INTENDED TO BE USED IN COMBINATION WITH THE DEVICE, IF ANY

Description of Accessories Intended to be Used in Combination with the Device

The Omnipod 5 App is a required accessory. You must have the App to enter your settings, set up a Pod, and deliver mealtime and correction boluses (doses) of insulin.

The Omnipod 5 App comes installed on a Controller (handset for remote control of the Omnipod 5 Pod) supplied by Insulet Corporation.

Description of Other Devices and Products Intended to be Used in Combination with the Device

Dexcom G6: Dexcom G6 Continuous Glucose Monitoring System and the Dexcom G6 Mobile App are required for use of Omnipod 5's Automated Mode.

RISKS AND WARNINGS

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

If, during the use of this device or because of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative (contact information provided in Section 1 of this SSCP) and to your national authority. The contacts of

national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:

https://ec.europa.eu/health/md_sector/contact_en

HOW RISKS HAVE BEEN MANAGED

Insulet has reviewed possible risks that could happen while using Omnipod 5. Insulet complies with relevant international standards for determining risks. These potential risks are identified through several sources including subject matter expertise, Competent Authority database review, product complaints, and literature review.

Table 2 below contains a summary of the potential risks associated with the use of Omnipod 5 and how the risk has been controlled.

Potential Risk	Risk Control or Management step
The Omnipod 5 System uses sensor glucose values and trends to calculate insulin delivery. If the sensor glucose values are inaccurate, the System could deliver an inaccurate dose of insulin which can lead to hypoglycaemia or hyperglycaemia	• Compatibility testing has been completed with the Dexcom G6 to understand the performance and accuracy characteristics of sensor glucose data provided to the Omnipod 5 System. • Instructions are provided in the User Guide
The Omnipod 5 System uses information and settings that you enter to calculate and adjust insulin delivery. If the information you enter is inaccurate, the System could deliver an inaccurate dose of insulin which can lead to hypoglycaemia or hyperglycaemia.	• The User's healthcare provider determines the information and settings to be entered as required for appropriate insulin delivery. • Instructions are provided in the User Guide
Wearing a Pod might cause infection, resulting in bleeding, pain, and skin irritations, including redness.	• Selection of appropriate skin-tissue contacting materials known to be bio-compatible • Testing of the materials used in accordance with recognised international standards • Instructions are provided in the User Guide
Kinks in the cannula or dislodging of the cannula can affect insulin delivery. Glucose that does not decrease after a bolus, or other unexplained high glucose, are signs of a blockage and an interruption in insulin delivery	• The presence of a viewing window on the edge of the Pod to verify the cannula is inserted into the skin • The Omnipod 5 System is designed with an alarm in the event of a blockage being detected. Details are provided in the accompanying User Guide

	• Appropriate guidance, including a troubleshooting guide is provided within the User Guide
Air bubbles in the Pod or cannula can affect insulin delivery. If there is a large amount of air in the Pod, the System could deliver an inaccurate dose of insulin which can lead to hypoglycaemia or hyperglycaemia.	• Appropriate guidance, including occlusion troubleshooting is provided within training, with ongoing supervision of the user's healthcare provider. • Appropriate guidance, including a troubleshooting guide is provided within the User Guide
Infusion site complications like scar tissue and infection can make insulin delivery less effective. Glucose that does not decrease after a bolus, or other unexplained high glucose, is a sign of ineffective insulin delivery.	• Appropriate guidance, including occlusion troubleshooting is provided within training, with ongoing supervision of the user's healthcare provider. • Appropriate guidance, including a troubleshooting guide is provided within the User Guide
Hardware defects, software glitches, and Pod failures can lead to hypoglycaemia, hyperglycaemia, or diabetic ketoacidosis.	• The Omnipod 5 System is designed with alarms in the event of issues such as a blockage being detected, a system error, or a Pod shutdown. Details are provided in the User Guide • Appropriate guidance, including a troubleshooting guide is provided within the User Guide

Table 2: Hazardous situations with associated patient harm

REMAINING RESIDUAL RISKS AND UNDESIRABLE EFFECTS

The most severe risks related to an insulin delivery system like Omnipod 5 are considered severe hypoglycaemia (low glucose) and DKA (diabetic ketoacidosis).

The likelihood of severe low glucose while using Omnipod 5 is estimated to be over 20 times lower than the acceptable safety goal for this risk.

The likelihood of DKA while using Omnipod 5 is estimated to be 70 times lower than the acceptable safety goal for this risk.

Table 3 shows details of potential risks remaining. The table shows details of the likelihood of these risks, either from data generated by the Insulet Corporation, or taken from relevant published literature of similar devices.

Residual risks / undesirable effect	Associated potential risk severity	Reported estimate of the likelihood of risk occurrence	Safety Objective
Severe Hypoglycaemia (low glucose):	Significant*	fewer than 1 in 1,000 events per person month[1]	Fewer than 21 in 1,000 events per person month[2]
DKA (Diabetic Ketoacidosis):		fewer than 1 in 5,000 events per person month[1]	fewer than 14 in 1,000 events per person month[2]

*Significant is defined as 'having the potential to result in injury or impairment that is reversible with medical intervention'.

Table 3: Reported Residual risks / undesirable effects

[1] Insulet CER DD-003091

[2] T1D Exchange Registry Study data based on published rates from the following publications:

Foster NC et al., "State of Type 1 Diabetes Management and Outcomes from the T1D Exchange in 2016-1018" Diabetes Technology Ther. Volume 21(2) pp. 66-72 (2019).

Miller KM, Foster NC, Beck RW, Bergenstal RM, DuBose SN, DiMeglio LA, Maahs DM, Tamborlane WV, T1D Exchange Clinic Network. Current state of type 1 diabetes treatment in the US: updated data from the T1D Exchange clinic registry. Diabetes Care. 2015;38(6):971-8.

WARNINGS AND PRECAUTIONS

Note: Below is a sample of important warnings and precautions. Refer to the Omnipod 5 User Guide for the full list of warnings and precautions.

Warnings & Precautions for Patients

- DO NOT start to use your system or change your settings without adequate training and guidance from your healthcare provider. Initiating and adjusting settings incorrectly can result in over-delivery or under-delivery of insulin, which could lead to hypoglycaemia or hyperglycaemia. Settings that impact insulin delivery mainly include: Pod Shut-Off, basal rate(s), Max Basal Rate, Max Bolus, Correction Factor(s), Insulin to Carb (IC) Ratio(s), Minimum Glucose for Calculations, Target Glucose and Correct Above, and Duration of Insulin Action.

- ALWAYS be aware of your current sensor glucose value, trust how your body feels, and do not ignore symptoms of high and low glucose. Even though insulin delivery adjusts automatically in Automated Mode with the goal of bringing your glucose level to your defined Target Glucose, severe hypoglycaemia or hyperglycaemia may still occur.

  If your sensor glucose values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or Sensor calibration if necessary. ALWAYS switch to Manual Mode if you feel you are receiving inaccurate CGM values.

    - Erroneously high CGM values can cause excessive insulin delivery, leading to severe hypoglycaemia, seizure, loss of consciousness or death.

    - Erroneously low CGM values can cause prolonged insulin suspension leading to hyperglycaemia, DKA, or death.

  If you are having symptoms that are not consistent with your blood glucose readings and you have followed all instructions described in the User Guide, contact your healthcare provider.

- DO NOT wait to treat hypoglycaemia (low glucose) or symptoms of hypoglycaemia. Even if you cannot check your glucose, waiting to treat symptoms could lead to severe hypoglycaemia, which can lead to seizure, loss of consciousness, or death.

- ALWAYS promptly treat hyperglycaemia (high glucose) according to your healthcare provider's recommendations. Symptoms of hyperglycaemia include fatigue, thirst, excess urination, or blurry vision. If left untreated, hyperglycaemia can lead to diabetic ketoacidosis (DKA), or death. DO NOT wait to treat DKA. If left untreated, DKA can quickly lead to breathing difficulties, shock, coma, or death.

- ALWAYS keep an emergency kit with you to quickly respond to any diabetes emergency or in the case that your Omnipod 5 System stops working. Always carry supplies to perform a Pod change should you need to replace your Pod at any time.

- ONLY use rapid-acting U-100 NovoLog®/NovoRapid® (insulin aspart), Humalog® (insulin lispro), and Admelog®/Insulin lispro Sanofi® (insulin lispro) insulin in the Omnipod 5 System as they have been tested and found to be safe for use with this system.

- Read all the instructions provided in the referenced User Guide, and the section titled 'SUGGESTED PROFILE AND TRAINING FOR USERS' within this SSCP, before using the Omnipod 5 System.

SUMMARY OF ANY FIELD SAFETY CORRECTIVE ACTION, (FSCA INCLUDING FSN) IF APPLICABLE

A Field Safety Corrective Action (FSCA) is an action taken by a manufacturer to report any reason leading to the device being changed or recalled from the market so that it cannot be bought and used. If taken off the market, any problems can be safely fixed before the device is sold again.

At the time of the latest revision of this SSCP, there has been one FSCA for Omnipod 5.

Date:	Action Type	Description:	Market(s) Affected
14-Nov-2022	Medical Device Correction	Omnipod 5 Controller charging port and cable damage due to heat generated by a poor connection between the cable and the port.	USA

SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

CLINICAL BACKGROUND OF THE DEVICE

Type 1 diabetes (T1D) is a chronic metabolic disorder where the cells in your pancreas can no longer make the insulin your body needs to change food into energy. The cells (called beta cells, or β -cells) that make insulin are destroyed by your body's own immune system. Type 1 diabetes was once thought to be more common in childhood, but it can be diagnosed at any age. (Chalakova T, 2021) (Schoelwer MJ, 2021).

People with T1D need to monitor their glucose frequently and self-inject with appropriate amounts of insulin. To achieve optimal care, people with diabetes must carefully plan their schedules around their care activities. They also have to make frequent difficult decisions and calculations about their treatment, diet, and activities. This burden of care can cause distress and frustration among people living with T1D, especially among those who struggle to reach their glucose goals.

Automated insulin delivery systems are a safe and effective approach for people with diabetes. Today, decisions about the most appropriate treatment for someone with diabetes is complex. Each person must work with their care team to find the best choice for them. There are many systems available so that people can choose what best fits their needs.

Outpatient use of automated systems has been proven to be safe. These systems improve outcomes compared to other insulin therapies. Use of these systems has shown a decrease in A1c, increase in time-in-range, and reduced time spent with low and high glucose. Studies have also shown improvement in fear of lows, quality of life, treatment satisfaction, and diabetes distress, while the number of people with poor sleep quality was reduced.

Omnipod 5 is intended to reduce the frequency, severity, and length of both high and low glucose. It increases, decreases, and pauses insulin delivery to keep glucose at a recommended target level and reduce swings in glucose.

THE CLINICAL EVIDENCE FOR THE CE-MARKING

Completed clinical studies include:

- **Evaluating the Safety and Effectiveness of the Omnipod Horizon™ Automated Glucose Control System in Patients with Type 1 Diabetes NCT04196140**

  This study investigated the safety and efficacy of the Omnipod 5 System in 240 people with type 1 diabetes ages 6 to 70 years old. Participants used their usual therapy for 2 weeks, followed by 13-weeks using Omnipod 5 and a 12 month extension. Omnipod 5 was found to be safe and effective during 15 months of total use.

  Link to publication: https://doi.org/10.2337/dc21-0172

  Link to abstract: https://diabetesjournals.org/diabetes/article/71/Supplement_1/33-OR/146776/33-OR-ADA-Presidents-Select-Abstract-Glycemic

- **Evaluating the Safety and Effectiveness of the Omnipod Horizon™ Automated Glucose Control System in Children with Type 1 Diabetes Aged 2.0-5.9 years: Preschool Cohort NCT04476472**

  This study assessed the safety and efficacy of the Omnipod 5 System in 80 people with type 1 diabetes ages 2 to 5.9 years old. Participants used their usual therapy for 2 weeks, followed by 13-weeks using Omnipod 5 and a 9 month extension. Omnipod 5 was found to be safe and effective during 12 months of total use.

  Link to publication: https://doi.org/10.2337/dc21-2359

  Link to abstract: https://diabetesjournals.org/diabetes/article/71/Supplement_1/33-OR/146776/33-OR-ADA-Presidents-Select-Abstract-Glycemic

- **Prepivotal Evaluation of the Safety and Effectiveness of the Omnipod Horizon Automated Glucose Control System in Patients with Type 1 Diabetes NCT04176731**

  This study evaluated the efficacy and safety of the Omnipod 5 algorithm's Target Glucose setting options in 36 people with type 1 diabetes ages 6 to 70 years old. Participants used their usual therapy for 2 weeks, followed by 2 weeks using Omnipod 5 at different Target Glucose settings. All five options for Target Glucose were found to be safe and effective.

  Link to publication: https://doi.org/10.1089/dia.2020.0546

- **Evaluating the Safety and Effectiveness of the Omnipod Horizon™ CGM-informed Bolus Calculator in Patients with Type 1 Diabetes NCT04320069**

  This study looked at the safety of the Omnipod 5 SmartBolus Calculator in 25 people with type 1 diabetes ages 6 to 70 years old. The participants used Omnipod 5 in Manual Mode for 7 days without a connected glucose sensor, followed by 7 days with a connected glucose sensor. The CGM-informed SmartBolus Calculator showed results of less time in hypoglycaemia within 4 hours of a bolus.

  Link to publication: https://doi.org/10.1089/dia.2021.0140

- **Evaluating the Safety and Effectiveness of the Omnipod 5 Automated Insulin Delivery System in Patients with Type 2 Diabetes NCT04617795**

  This feasibility study evaluated the safety and efficacy of the Omnipod 5 System in 24 people with type 2 diabetes ages 18-75 years. All participants used their usual therapy for 2 weeks followed by 8 weeks of Omnipod 5 System use with the caveat that those previously on basal insulin-only used Omnipod 5 in manual mode for 2 weeks before the 8-week Omnipod 5 phase. Omnipod 5 was found to be safe and effective.

- **Automated Insulin Delivery for INpatients With DysGlycemia (AIDING) Feasibility NCT04714216**

  This feasibility study evaluated the feasibility, safety, and efficacy of the Omnipod 5 System in 16 people with type 1 and type 2 diabetes in non-ICU medical surgery units. All participants used the Omnipod 5 System until discharge or up to 10 days. The system was found to be feasible, safe, and effective.

Ongoing clinical studies include:

- **Efficacy and safety of the Omnipod 5 System Compared to Pump Therapy in the Treatment of Type 1 Diabetes: a Randomized, Parallel-group Clinical Trial NCT05409131**

  The objective of this study is to evaluate the safety and efficacy of the Omnipod 5 System compared to pump and continuous glucose monitor (CGM) therapy in people with type 1 diabetes ages 18 – 70 years old. Participants will use their usual therapy for 2 weeks, followed by randomization to either Omnipod 5 with Dexcom G6 CGM or the participant's current insulin pump with Dexcom G6 CGM for 13 weeks.

AN OVERALL SUMMARY OF THE CLINICAL SAFETY

As shown through clinical studies, among current diabetes treatment options, Omnipod 5 is a state-of-the-art choice. The benefit/risk profiles that support the safety of the device for the people who will use it are acceptable. The Omnipod 5 Automated Insulin Delivery System conforms with the GSPRs as stated in MDR (2017/745). Omnipod 5 is safe for use during the day and night.

Insulet meets the requirements of the MDR (2017/745) for monitoring ongoing device safety through its Post Market Surveillance procedures. These procedures are used with other technical documentation as the basis for the information in this summary.

POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

When considering alternative treatments, it is recommended to contact your healthcare professional who can consider your individual situation.

Background on Available Therapeutic Options

Keeping glucose in a target range (3.9–10.0 mmol/L; 70–180 mg/dL) can help prevent complications related to high glucose (>10.0 mmol/L; >180 mg/dL) and low glucose (<3.9 mmol/L; <70 mg/dL). (Wilmot EG, 2021) (Tyler NS, 2020) Prolonged exposure to high glucose can result in complications throughout the body, including several macrovascular (ischemic heart disease, stroke and peripheral artery disease) and microvascular (neuropathy, nephropathy and retinopathy) complications. Increased fasting glucose variability was also shown to be associated with higher risk of severe low glucose and all-cause mortality. (Chalakova T, 2021) (Wilmot EG, 2021) (Cobry EC B. C., 2020). (Cernea S, 2020).

Despite advancements in treatment methods and better access to diabetes tools, many people with T1D still struggle to reach recommended A1c goals. Between 2016 and 2018, only 17% of youth and 21% of adults were meeting goals recommended by the American Diabetes Association (ADA). (Wilmot EG, 2021)

Diabetes researchers and innovators are finding many promising methods to help people with insulin-requiring diabetes. These methods are described below.

GENERAL DESCRIPTION OF AND BENEFITS-RISKS OF THERAPEUTIC ALTERNATIVES

People with type 1 diabetes have several choices for insulin delivery therapy. Some therapies are more invasive than others and may carry greater risks. All therapies carry the risk of severe low and high glucose. You can work with your healthcare team to understand your options.

Examples of more invasive therapies include:

- Implantable Insulin Pumps
- Pancreas and Islet Transplant

Examples of less invasive therapies include:

- Multiple Daily Injections
- Insulin Pumps (with or without use of a glucose sensor)
- Automated Insulin Delivery (AID) systems

SUGGESTED PROFILE AND TRAINING FOR USERS

Insulet puts all its devices through a process called human factors and usability testing. This process makes sure that a device is safe to use by a wide variety of people. Insulet's testing process complies with international standards for this type of testing.

Through this testing, Insulet has shown that all Omnipod 5 System users need to meet the following requirements:

- You will follow the instructions from your Healthcare Provider who will coordinate the appropriate training with you.
- You must be willing to use the device and monitor your glucose as described in the User Guide, the CGM manufacturer's instructions, and as trained and instructed by your healthcare provider and Omnipod 5 Trainer.
- You have adequate vision and/or hearing to recognise all functions of the Omnipod 5 System including alerts, alarms, and reminders according to instructions.

REVISION HISTORY

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
Revision 0 (Version 1)	*14-Mar-2023*	*Removal of references to system control via third-party mobile phone;* *Update of Clinical study data.*	☒ *Yes* *Validation language: English* ☐ *No (only applicable for Class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)*
Revision 1 (Version 2)	*31-May-2023*	*Amendment of basic UDI-DI*	☒ *Yes* *Validation language: English* ☐ *No (only applicable for Class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)*